Exhibit A

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Drug Information Services Branch (HFD-84)
Center for Drug Evaluation and Research, Food and Drug Administration
5600 Fishers Lane, Rockville, MD 20857

Re: Zocor® Orange Book Listings
U.S. Patents RE36,481 and RE36,520
Kenyon Ref. 1907/45301

Dear Sir or Madam:

This is a notice pursuant to 21 C.F.R. 314.53(f) notifying the Agency that information published by the FDA in Approved Drug Products and Therapeutic Equivalents Thereof (the "Orange Book"), namely, the listing of U.S. Pats. Nos. RE36,481 and RE36,520 with respect to Zocor®, is inaccurate and irrelevant. Pursuant to 314.53(f), please forward this letter to the applicant, Merck & Co. Inc., that it may withdraw these patents from the Orange Book.

Zocor contains a single active ingredient, simvastatin. RE 36,481 and RE 36,520 do not claim simvastatin, or a method of using simvastatin. They claim different compounds, which are said to be metabolites of simvastatin.

The FDA has clarified that metabolite patents are not properly listed in the Orange Book.

> **The final rule prohibits submission of patents claiming metabolites when the metabolite is not the active ingredient described in the NDA.** The submission of a metabolite patent does not meet the legal requirements for patent submissions as discussed in the proposed rule (see 67 FR 65448 at 65451).

68 Fed. Reg. 36675, 36680 (June 18 2003)

Following issuance of the final rule, brand name companies have asked the FDA to remove patents from the Orange Book which are not properly listed in the Orange Book under the new regulations. For example, GlaxoSmithKline has requested that the FDA remove product-by-process patents listed with respect to Paxil®.

Still other companies have requested that the FDA remove metabolite patents from the Orange Book even before the FDA's regulations became effective. Bristol-Myers Squibb asked the FDA to remove patents claiming metabolites from the BuSpar® and Serzone® Orange Book listings; and Aventis asked the FDA to remove a patent claiming a metabolite of leflunomide from the Arava® Orange Book listing.

These companies were evidently aware of the substantial potential liability which could result from failure to voluntarily remove improperly listed patents from the Orange Book. (It was reported that Bristol-Myers Squibb settled actions relating to the improper listing of the Buspar metabolite patent for $640 million dollars.)

Like the Bristol-Myers Squibb metabolite patent, Merck's improperly listed metabolite patents may have the effect of improperly delaying generic competition for Zocor. If Merck, the applicant, is concerned about the possibility of improperly delaying generic competition, it should immediately direct the FDA to remove the RE36,481 and RE36,520 patents from the Orange Book.

Very truly yours,

Steven J. Lee

Steven J. Lee, Esq.